



UNCLASSIFIED

Joint Program Executive Office for Chemical and Biological Defense Medical Virtual Industry Day

Joint Program Executive Office for Chemical and Biological Defense

Western Eastern Venezuelan Equine Encephalitis Vaccine (WEVEE)

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Distribution Statement A: Approved for public release; distribution is unlimited.



Disclaimer



- While we are presenting our currently planned Business Opportunities, we recognize that these may change given our changing fiscal environment and the strategic guidance of the Department of the Defense.
- New starts and increases to production levels in FY13 will be delayed until the Appropriations Bill is passed.



Capability Gap & Product Description



Capability Gap:

- There are no FDA-approved prophylactic or antiviral medical countermeasures against Western, Eastern and Venezuelan Equine Encephalitis Virus

Product Description:

FDA approved trivalent vaccine that will protect against aerosolized exposure to WEEV, EEEV, and VEEV



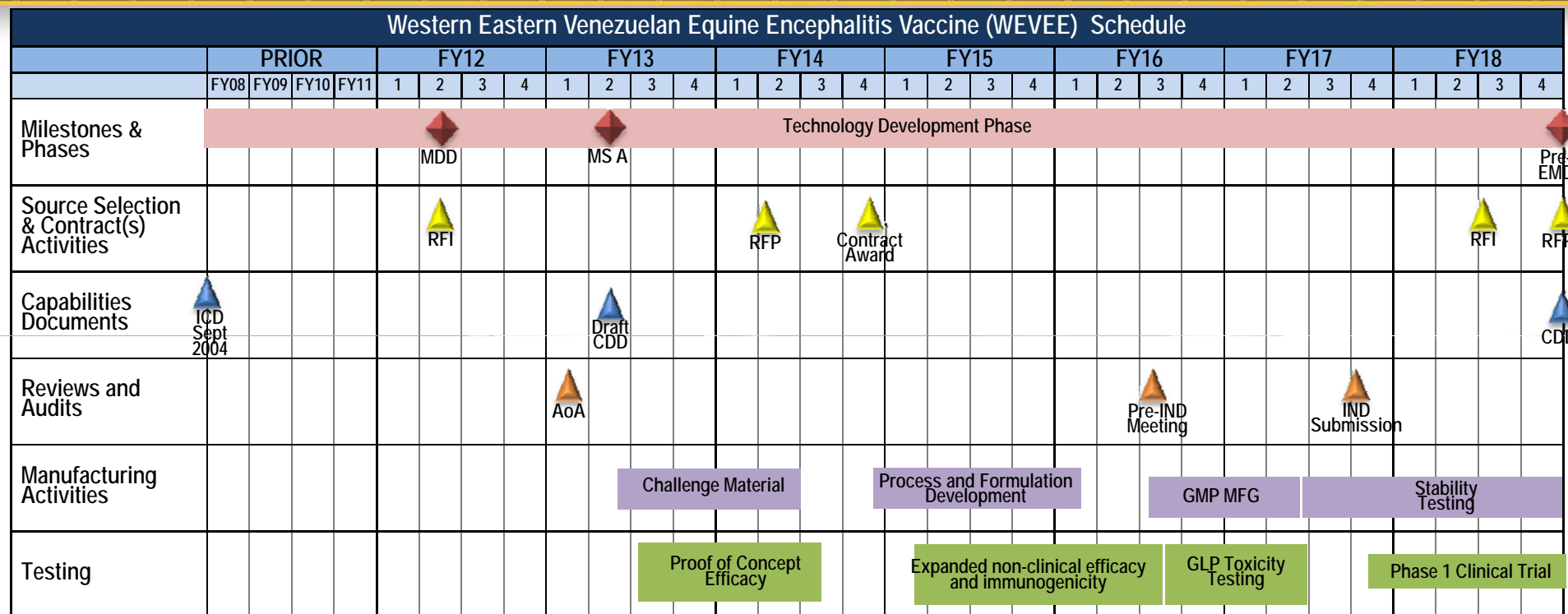
Product Fit in the Family of Systems

- The WEVEE vaccine is part of a family of systems that protect the Warfighter from biological warfare





WEVEE Product Schedule



- Program Initiation at Milestone A in 2QFY13
- RFP Solicitation in 1QFY14 includes
 - Process and Formulation Development
 - GMP manufacturing
 - Stability Testing
- RFP Solicitation at Pre-EMD in 4QFY18 for Prime Systems Contractor



Acquisition and Contracting Strategy



Strategy:

Leverage current contracts and Interagency collaborations to evaluate multiple prototypes in the Technology Development Phase

Status:

- Milestone A to Milestone B
 - JVAP will serve as the integrator
 - Government will serve as Regulatory Sponsor
 - RFP for Manufacturing following MS A (2QFY14)
- Milestone B to Licensure
 - Prototype down select at MS B
 - RFP for Prime Systems Contractor at Pre-EMD (4QFY18)
 - To include procurement options
 - Prime Systems Contractor will serve as Regulatory Sponsor



Technology Gap



- There are no FDA-approved products to provide protection against an aerosol or endemic exposure
- Current IND products have poor tolerability and efficacy limitations against aerosol exposure
- Animal models are immature for both small and large animal models



Business Opportunities



- **Anticipated 4QFY14 contract award for manufacturing**
 - Released Request for Information 16 Aug 12 – Process development and manufacturing of VLP, VRP, and/or DNA Vaccines
 - Anticipate Request for Proposal release 2QFY14
- **Explore opportunities for animal model development, analytical assay development, and competitive prototyping through task order vehicles, CBMS BAA, and Interagency collaborations**
 - Small animal model development and qualification
 - Passive transfer and correlates of protection assay development
 - Advanced development studies to evaluate WEVEE vaccine prototypes



Points of Contact



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Acronym Glossary



ADM: Acquisition Decision Memorandum or Advanced Development & Manufacturing

AoA: Analysis of Alternatives

APUC: Acquisition Procurement Unit Cost

AS: Acquisition Strategy

BARDA: Biomedical Advanced Research and Development Authority

BBP: Better Buying Power

BLA: Biologics License Application

BSV: Biosurveillance

CBMS: Chemical Biological Medical Systems

CDD: Capability Development Document

CPD: Capability Production Document

cGMP: Current Good Manufacturing Practice

CONOPS: Concept of Operations

CPIF: Cost Plus Incentive Fee

DARPA: Defense Advanced Research Projects Agency

DHS: Department of Homeland Security

DoD: Department of Defense

DSTL: Defense Science Technology Laboratory

DTRA/JSTO: Defense Threat Reduction Agency/Joint Science and Technology Office

EMD: Engineering Manufacturing and Development

EPA: Environmental Protection Agency

FDA: US Food & Drug Administration

FFP: Fixed Firm Price

FOC: Full Operational Capability

FRP: Full Rate Production

FY: Fiscal Year

HHS: Health and Human Services

IBR: Integrated Baseline Review

ICD: Initial Capabilities Document

IND: Investigational New Drug

IOC: Initial Operational Capability

JILA: Joint Integrated Logistics Assessment

JPEO: Joint Program Executive Office(r)

JPM: Joint Project/Product Manager

JPM-ADM: Joint Project Manager- Advanced Development & Manufacturing

JPMO: Joint Project/Product Management Office

JRO-CBRND: Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense

JVAP: Joint Vaccine Acquisition Program

KPP: Key Performance Parameter

KSA: Key System Attribute

LCCE: Life Cycle Cost Estimate

LCMP: Life Cycle Management Plan

LCSP: Life Cycle Sustainment Plan

LRIP: Low Rate Initial Production

MDA: Milestone Decision Authority

MIT: Medical Identification and Treatment Systems

MS: Milestone

MSR: Manufacturing Sustainment Rate

NDA: New Drug Application

NGDS: Next Generation Diagnostic System

NIH: National Institutes of Health

NTA: Non-Traditional Agent

O&M: Operation and Maintenance

OASD (HA): Office of the Assistant Secretary of Defense (Health Affairs)

OGA: Other Government Agency

OSD (NCB/CB): Office of the Secretary of Defense (Nuclear/Chemical Biological)

OSTP: Office of Science and Technology Policy

OUSD(C): Office of the Under Secretary of Defense (Comptroller)

PAIO: Joint CBRN Defense Program Analysis Integration Office

RDTE: Research, Development, Test and Evaluation

RFP: Request For Proposal

SEP: Systems Engineering Plan

SNS: Strategic National Stockpile

SPA: Special Protocol Assessment

TD: Technology Development

TDP: Technical Data Package

TED: Troop Equivalent Dose

THP: Trained Health Care Provider

TMT: Transformational Medical Technologies

TOA: Total Obligation Authority

TRA: Technology Readiness Assessment

TRL: Technology Readiness Level

USAMMDA: US Army Medical Materiel Development Activity

USAMRIID: US Army Medical Research Institute of Infectious Disease

USAMRICD: US Army Medical Research Institute of Chemical Defense

USAMRMC: US Army Medical Research and Materiel Command